A Randomized Controlled Trial Comparing Mandibular Local Anesthesia Techniques in Children Receiving Nitrous Oxide–Oxygen Sedation

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The aim of this study was to test the hypothesis that dental pain control using infiltration/intrapapillary injection was less effective than inferior alveolar block/long buccal infiltration anesthesia in children. A total of 101 healthy children, aged 5–8 years, who had no contraindication for local anesthetic and who needed a pulpotomy treatment and stainless steel crown placement in a lower primary molar were studied. A 2-group randomized blinded controlled design was employed comparing the 2 local anesthesia techniques using 2% lidocaine, 1 : 100,000 epinephrine. All children were given 40% nitrous oxide. Children self-reported pain using the Color Analogue Scale. The study was conducted in a private pediatric dental practice in Mount Vernon, Wash. Overall pain levels reported by the children were low, and there were no differences between conditions at any point in the procedure. Pain reports for clamp placement were block/long buccal 2.8 and infiltration/intrapapillary 1.9 ($P = .1$). Pain reports for drilling were block/long buccal 2.0 and infiltration/intrapapillary 1.8 ($P = .7$). Nine percent of children required supplementary local anesthetic: 4 of 52 (7.7%) in the block/long buccal group and 5 of 49 (10.2%) in the infiltration/intrapapillary group ($P = .07$). The hypothesis that block/long buccal would be more effective than infiltration/intrapapillary was not supported. There was no difference in pain control effectiveness between infiltration/intrapapillary injection and inferior alveolar block/long buccal infiltration using 2% lidocaine with 1 : 100,000 epinephrine when mandibular primary molars received pulpotomy treatment and stainless steel crowns.

Key Words: Randomized controlled trials; Anesthesia, dental; Child.

Surprisingly, the American Academy of Pediatric Dentistry's current reference manual lacks a section on pain control.[1] This inattention may reflect lack of consensus on the effectiveness of pain control strategies. This current study suggests that it is possible to definitively address these questions. Pain control guidelines have been developed in other areas of medicine and might serve as a model.[2,3]

Three major studies have sought to evaluate the use of infiltration as an alternative to inferior alveolar block in children.[4–6] A fourth study assessed the effectiveness of infiltration anesthesia without any comparison group.[7] The primary rationale for these studies has been that infiltrations employ lower doses of local anesthetics and therefore increase the safety of treatment.[8] In addition, the infiltration is perceived as less stressful for both child patient and dentist. Two comparison studies found no difference in efficacy overall. However, of particular interest is the suggestion in the third study that infiltration was less effective than block for pulpotomy.[6] However, none of these studies was designed to defini-

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tively address this question. The fourth study had a relatively high rate of apparent anesthetic failure using infiltrations alone in the mandible.

A recent observational study by pediatric dental specialists found that 11.6% of children undergoing dental treatment had ineffective pain control.[9] These observations again suggested that local anesthesia was less effective when the treatment was extractions and pulp treatments. The dentists who were observed were fairly representative of those in community practice, and a substantial minority was found to use infiltration in the mandible. Again, however, the study was not designed to definitively address the efficacy of infiltration, and measures of pain and anxiety were confounded.

The aim of this study was to test the hypothesis that pain control using infiltration/intrapapillary injections was less effective than block/long buccal infiltration anesthesia in children aged 5–8 years undergoing pulpotomies in mandibular primary molars.

METHODS

Subjects

Healthy children who needed a pulpotomy treatment in a lower primary molar and had no contraindication for local anesthetic were eligible for the study. On the day of treatment, after the initial consultation, parents of eligible children requiring pulpotomy were approached by office staff and informed of the study; written informed consent of the parent and assent of the child were then obtained. There were few refusals. A total of 106 children aged 5–8 years were initially enrolled. A total of 55 girls with average age of 76 months (SD = 11 months) and 46 boys with an average age of 79 months (SD = 13 months) completed the study. One child was withdrawn after consenting but before participation. Four study forms were misplaced after data collection, and those children were excluded. The study was approved by the Institutional Review Board of the University of Washington.

Design

A 2-group randomized blinded controlled design was employed. The study was conducted in a private pediatric dental practice in Mount Vernon, Wash.

Measures

Primary Outcome Measure. Assessment of the level of pain experience by the child was measured using the Color Analogue Scale (CAS).[10] The CAS is a vertical 14.5-cm scale that is graduated from white at the bottom, where it is labeled "No Pain," to very red at the top where it is labeled "Most Pain." The child uses a sliding marker to give pain reports. Children aged 5 and above have been shown to be able to use such scales.[11–13] In this study, the scale was increased proportionately in size to a length of 21 cm, with the same gradation in color. This was to allow the child to hold the scale rigidly and be able to move the marker easily from a supine position in the dental chair. The scale has a numerical scale on the back from 0 to 10, with 0.25 gradations, so the administrator of the measure could quickly determine the number representing the child's pain level.

Each child was pretested with the CAS by the research staff to make sure he or she was able to comprehend and use the scale. Five nondental questions relating to situations of pain with various intensities were asked. Children who were not able to use the CAS effectively were excluded.

Dentist Measure. A 3-category scale was used by the clinician to rate the effectiveness of the local anesthesia. The categories were effective, partially effective, and ineffective.

Other Measures. Paper and pencil measures were completed in the waiting room prior to treatment. The Dental Subscale of the Children's Fear Survey Schedule (CFSS-DS) was used to assess dental fear.[14] This inventory consists of 15 items and uses a 5-point Likert format with item scores ranging from 1 (not at all) to 5 (very afraid). Total scores range from 15 to 75, with scores exceeding 37 indicating high fear.[15] Parents completed a symptom questionnaire that asked if the child had acute dental pain prior to the appointment.

Conditions

All children were given 40% nitrous oxide via a nasal mask. After 3 minutes, the site of the injection was dried with a cotton tip applicator, and topical anesthetic (Hurricaine, 20% benzocaine gel) was applied for 60 seconds. The dental hygienist then opened an envelope giving the anesthetic assignment, and local anesthetic was administered. The same dental hygienist gave all the injections. Local anesthetic was administered without the dentist present. Children were randomly assigned to either the infiltration or block group using a computer algorithm (Microsoft Excel RAND function).

Two dentists performed all of the dental treatment in this study. The dentists were blind to anesthetic condition.

For the infiltration, a 27-gauge short needle was directed toward the apex of the tooth in the mucobuccal fold, and most of 1 cartridge (1.8 mL) of 2% lidocaine,

1 : 100,000 epinephrine was used. In addition, intrapapillary injections mesial and distal to the tooth were given.

For the inferior alveolar block, a 27-gauge short needle was placed medial to the internal oblique ridge with the barrel angled over the primary molars on the opposite side of the arch and advanced approximately 15 mm. Approximately 1.6 mL of 2% lidocaine, 1 : 100,000 epinephrine were administered. The remaining 0.2 mL was used for the long buccal injection. For the long buccal, the tip of the needle was inserted distal and buccal to the most posterior tooth in the arch.

After the initial anesthetic, the rubber dam clamp was applied to the tooth to be treated and the pain score recorded from the child (CAS2). If the child reported any pain, additional anesthetic was given consistent with the original assignment. If the child reported any pain during tooth preparation, the procedure was immediately stopped and additional anesthetic was given according to the assignment, in half cartridge increments (0.9 mL). The CAS3 pain report was obtained after tooth preparation was completed.

Procedure

The CAS was used at 4 stages of treatment. The dental assistant asked the child to rate the pain of injection (CAS1). A minimum time of 3 minutes elapsed between the injection and when the rubber dam clamp was applied (CAS2). A clamp was used in all cases. If the child reported pain, additional anesthetic was given as described earlier. After the minimum time of 3 minutes had elapsed, the dentist approached the child to begin tooth preparation. If at any point during the treatment the dentist felt that the pain control was ineffective, the treatment was stopped and more local anesthetic was administered (Anesthetic 2). The tooth was prepared for a pulpotomy and for subsequent placement of a stainless steel crown. After entry into the pulp chamber and placement of medication, the child once again assessed pain (CAS3). The dental hygienist now returned to fit the stainless steel crown, and once the treatment was complete the child rated pain for the overall visit (CAS4). Each time the child was asked to report his or her pain, the research assistant said, "Slide the marker up the scale to show how much pain or hurt you felt. Remember the bottom is no pain or hurt at all and the top is the most pain or hurt imaginable." All cases were videotaped to keep check for violations of the protocol.

At the completion of treatment, the dentist rated the effectiveness of pain control and also guessed which type of injection he or she thought the child had. The dentist also completed the Frankl scale. Dental assistants called the parent the next day regarding their child's behavior or problems after dental treatment. .

Data Analysis

A Student's *t* test was used to test the primary hypothesis that children who receive infiltration/intrapapillary anesthesia will have a higher CAS score (that is, report greater pain during treatment) than children who receive block/long buccal infiltration anesthesia. The 101 analyzable subjects in this study make it adequately powered to detect a treatment group difference in CAS score of 1.5, which was deemed a clinically significant difference by study investigators. Assuming a common standard deviation of 2.7 and a significance (alpha) level equal to .05, the study has 79.7% power to detect a CAS score difference of 1.5. Fisher's exact test was used to test the secondary hypothesis that supplementary anesthetic will be given more often in the infiltration/intrapapillary group than the block/long buccal group. Similarly, a *t* test was used to examine the hypothesis that children with high preoperative dental anxiety (CFSS-DS) report higher CAS scores overall than children with low or moderate anxiety. The data were analyzed using SPSS 10.0 for Windows.

RESULTS

The mean age of children in both groups was 78 months (SD = 12 months). Thirty girls were randomized into the block group and 25 girls to the infiltration group. There was no difference in the average age or proportion of girls in each group (both $P > .05$). Eight children (15.4%) in the block group had previous symptoms from the tooth being treated, and again 8 children (16.7%) from the infiltration group had previous symptoms ($P = .9$). Roughly half of all pulpotomies were on the first primary molar only, one quarter of all pulpotomies were on the second molar only, and the remaining involved both molars. There was a good distribution of all 3 combinations of teeth treated in both groups ($P = .3$). The average time interval from the injection to start of the tooth preparation was 14 minutes (SD = 5 minutes) in the block group and 15 minutes (SD = 4 minutes) in the infiltration group ($P = .3$).

Overall pain levels reported by the children were low, and there were no differences between conditions at any point in the procedure. There were no differences in the results for children treated by the 2 different dentists. The data are in Tables 1 and 2. Similarly, there was no difference in injection pain reported by the groups (CAS1; see Table 3).

Nine children (9%) required additional anesthetic: 4

Table 1. Mean Self-reported Pain After Rubber Dam Clamp Application (CAS2) for Children Who Received an Inferior Alveolar Block/Long Buccal Infiltration Versus Infiltration/Intrapapillary Injection

Treatment Group	*n*	*Mean CAS2*	*SD*	*P value*
Block	52	2.83	2.89	.10
Infiltration	49	1.89	2.89	

of 52 (7.7%) children were in the block/long buccal anesthesia group, and 5 of 49 children (10.2%) were in the infiltration/intrapapillary injection group ($P = .7$). No child received more than 1 additional cartridge of anesthetic. As with the CAS self-report measure, the hypothesis that a larger proportion of children in the infiltration/intrapapillary group would require supplemental anesthesia was not supported. Six of 9 children requiring additional anesthetic were boys.

About 18% of the children who did not receive additional anesthetic were reported by parents as having pain prior to the appointment, whereas none of the 9 children who did receive additional anesthetic had parents report previous pain. Similarly with previous medication, 7.7% of the children who did not require additional anesthetic were reported by parents to have received medication for infection/pain prior to the appointment, whereas none of the 9 children who required additional anesthetic had received medications. The CAS3 and CAS4 scores were analyzed again after removing the children who needed additional anesthetic, and no differences between the groups were found. There were no differences between the groups for CFSS-DS, previous pain symptoms, or type of tooth or teeth treated. When parents were called the next day, there were no differences between the groups and no adverse reports of cheek or lip biting.

Table 4 gives the dentist ratings of anesthesia effectiveness. When the dentist rated the anesthetic as partially effective, the child CAS4 ratings (overall assessment of pain during the appointment) were significantly higher than when the dentist rated the treatment as effective ($P = .03$). However, the significance of this result disappears when you exclude from the analysis the children who received additional anesthetic ($P = .2$), although the direction of the relationship remains the same. No child was rated as having "ineffective" pain

Table 2. Mean Self-reported Pain After Drilling (CAS3) for Children Who Received an Inferior Alveolar Block/Long Buccal Infiltration Versus Infiltration/Intrapapillary Injection

Treatment Group	*n*	*Mean CAS3*	*SD*	*P value*
Block	52	2.02	2.48	.74
Infiltration	49	1.84	2.86	

Table 3. Mean Self-reported Pain of Injection (CAS1) for Children Who Received an Inferior Alveolar Block/Long Buccal Infiltration Versus Infiltration/Intrapapillary Injection

Treatment Group	*n*	*Mean CAS1*	*SD*	*P value*
Block	52	2.13	2.74	.77
Infiltration	49	1.98	2.66	

control. Analyses also showed that the dentist blinding was effective. The dentist guessed block anesthesia 72% of the time, showing bias toward the block being a more effective anesthetic method. When dentists guessed a block, they were correct 56.3% of the time, and when they guessed infiltration, they were correct 57.1% of the time ($P = .23$).

Overall the proportion of children who were fearful (CFSS-DS $\geq$ 37) was relatively high (32.6%). There was no difference in CAS4 (after drilling) between children who were rated as fearful and those who were rated as less fearful, and overall CAS scores were not higher for children who rated themselves as fearful ($P = .7$).

DISCUSSION

This clinical trial demonstrates no difference in pain control effectiveness between infiltration/intrapapillary injections and inferior alveolar block/long buccal infiltration for children undergoing mandibular pulpotomy and stainless steel crown placement.

These results fail to confirm suggested differences in 1 previous study.[6] Pain control was effective overall for 91% of children. This result is qualitatively similar to the 88% success rate reported in the previous observational study of pediatric dentists and to the 87% rate reported for general dentists.[9]

Nitrous oxide was used in all conditions, as this is a common agent in pediatric dental practice. This may, however, have resulted in an attenuation of pain. Pain reports (CAS2, CAS3, CAS4) are very low.[16] However, both treatment groups were treated identically.

The results were similar whether self-report or dentist ratings were used. Moreover, the result was the same for both anxious and less anxious children. Surprisingly,

Table 4. Dentist Ratings of Pain Effectiveness Related to Child Overall Self-report (CAS4) at the Conclusion of Treatment

Dentist Rating	*N**	*Mean CAS4*	*SD*	*P value*
Effective	89	1.88	2.37	.03
Partially effective	10	5.28	4.06	

* In some cases the dentists failed to rate pain effectiveness.

nearly one third of the children were reported to have high fear levels. This is in contrast to the findings of a recent observational study of pediatric specialist practices in Washington State where about 20% of children had high fear (K Baier, MD, unpublished data, 2002).

Among the strengths of this study are a blinded design with clearly defined interventions and outcome measures. Pain was self-reported by the children themselves. Checks were built into procedures to avoid protocol violations. On the other hand, the trial was conducted in a single practice that limits generalizability. Nevertheless, it is hoped that this and similar trials will lead to formal pain control guidelines for pediatric dental practice.

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